**UNITED STATES DISTRICT COURT**
**FOR THE WESTERN DISTRICT OF WISCONSIN**

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| ADAM STREETER, an individual,<br><br>Plaintiff,<br><br>v.<br><br>ELI LILLY AND COMPANY, a corporation; and DOES 1 through 50, inclusive,<br><br>Defendants. | ) | Case No. 3:14-cv-00555-slc |

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**DEFENDANT ELI LILLY AND COMPANY'S ANSWER TO COMPLAINT**

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In response to the Complaint ("Complaint") filed in this action by Plaintiff, Adam Streeter ("Streeter"), Defendant Eli Lilly and Company ("Lilly") answers Streeter's allegations in the numbered paragraphs of the Complaint.

**INTRODUCTION**

1. This is a civil action for products liability alleging personal injuries and damages, including serious and life-threatening withdrawal symptoms, suffered by Plaintiff Adam Streeter as a direct and proximate result of his ingestion and cessation of the prescription drug, Cymbalta (duloxetine), which is manufactured, marketed, and sold by Defendant Eli Lilly and Company (hereinafter, "Defendant" or "Lilly").

**ANSWER:** Lilly admits that it manufactures, markets, and sells Cymbalta®, for use only upon a prescription by a licensed physician, in accordance with applicable laws and regulations, and for its approved indications with FDA-approved warnings, precautions and other labeled risks and benefits of the medications. Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the remaining allegations in Paragraph 1 and therefore denies the same.

## PARTIES

2. Plaintiff Adam Streeter (hereinafter, "Plaintiff") is, and at all times relevant to this Complaint was, a citizen of the State of Wisconsin, County of Marathon.

**ANSWER:** Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 2 and therefore denies the same.

3. Defendant Eli Lilly and Company is, and at all times relevant to this Complaint was, an Indiana corporation with its headquarters in Indianapolis, Indiana. Lilly is a pharmaceutical company involved in the research, development, testing, manufacture, production, promotion, distribution, marketing and sale of numerous pharmaceutical products, including Cymbalta, a prescription antidepressant drug.

**ANSWER:** Lilly admits that it is an Indiana corporation with its principal place of business in Indianapolis, Indiana. Lilly also admits that it is engaged in the business of research, development, testing, manufacturing, producing, promoting, distributing, marketing, and selling prescription medications, including but not limited to Cymbalta®. Lilly denies the remaining allegations in Paragraph 3.

4. Plaintiff does not know the true names and identities of those defendants designated as DOES 1 through 50, inclusive, but alleges that each of said fictitiously named defendants was negligently and unlawfully responsible for the events herein described, and for the injuries and damages sustained by Plaintiff, Adam Streeter, and Plaintiff will ask leave of court to amend this complaint when the identity of each such fictitiously named defendant has been ascertained.

**ANSWER:** Lilly lacks knowledge or information sufficient to form a belief as to the truth of accuracy of the allegations in Paragraph 4 and therefore denies the same.

5. At all relevant times, each of the Defendants and their directors and officers acted within the scope of their authority. During the relevant times, Defendants possessed a unity of interest between themselves. As such, each Defendant is individually, as well as jointly and severally, liable to Plaintiff for Plaintiff's damages.

**ANSWER:** Paragraph 5 of the Complaint purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations.

## JURISDICTION AND VENUE

6. This Court has personal jurisdiction over Lilly insofar as Lilly is authorized and licensed to conduct business in Louisiana, maintains and carries on systematic and continuous contacts in this judicial district, regularly transacts business within this judicial district, and regularly avails itself of the benefits of this judicial district.

**ANSWER:** Lilly admits that it is authorized to conduct business and does conduct business in Louisiana, as alleged in Paragraph 6, and also in Wisconsin. Lilly denies the remaining allegations on the basis that they purport to allege conclusions of law and thus do not require a response.

7. Furthermore, Lilly has caused tortious injury by acts and omissions in this judicial district and caused tortious injury in this district by acts and omissions outside this district while regularly doing and soliciting business, engaging in a persistent course of conduct, and deriving substantial revenue from goods used or consumed and services rendered in this judicial district.

**ANSWER:** Paragraph 7 of the Complaint purports to allege conclusions of law and thus does not require a response and on that basis Lilly denies the allegations.

8. This Court has subject matter jurisdiction in the form of diversity jurisdiction, pursuant to 28 U.S.C.A. § 1332, in that there is a complete diversity of citizenship between Plaintiff and Defendant and the amount in controversy exceeds $75,000.00.

**ANSWER:** Lilly admits that this Court has subject matter jurisdiction in the form of diversity jurisdiction.

9. Venue is proper pursuant to 28 U.S.C. § 1391.

**ANSWER:** Paragraph 9 purports to allege conclusions of law and thus does not require a response and on that basis Lilly denies the allegations.

## FACTUAL ALLEGATIONS

10. Lilly is one of the largest pharmaceutical companies in the world with annual revenues exceeding $20 billion. A substantial portion of Lilly's sales and profits have been derived from its drug Cymbalta, whose 2009 annual sales exceeded $3 billion, making it the second most profitable drug in Lilly's current product line.

**ANSWER:** Paragraph 10 is vague and ambiguous as to time, content, and context and on that basis, Lilly denies the allegations.

11. Lilly has enjoyed considerable financial success from manufacturing and selling prescription drugs for the treatment of clinical depression, including the popular antidepressant Prozac (generically known as fluoxetine). Lilly launched Prozac in 1988 touting it as the first "Selective Serotonin Reuptake Inhibitor" ("SSRI"). SSRIs are a class of antidepressant drugs that were promoted as increasing the brain chemical serotonin in the synaptic clefts between the neurons in the brain. It has been theorized that reduced levels of serotonin cause depression; however, recent studies have undermined this theory. Prozac became extremely popular in the 1990s and was the top-selling antidepressant of its kind. Prozac's patent expired in August 2001.

**ANSWER:** Lilly admits that it researched, tested, developed, manufactured, labeled, marketed and sold Prozac®, for use only upon a prescription by a licensed physician, in accordance with applicable laws and regulations, and for its approved indications with FDA-approved warnings, precautions, and other labeled risks and benefits of the medication. Lilly admits that Prozac® is in the class of prescription medications known as selective serotonin reuptake inhibitors ("SSRIs"), but denies the relevance of the information. Lilly admits that the United States Food and Drug Administration ("FDA") approved Prozac® in 1987 as a safe and effective medication for the treatment of Major Depressive Disorder ("MDD"). Lilly admits that Prozac®'s patent expired in August 2001. Allegations pertaining to SSRIs as a class of antidepressants are vague and ambiguous as to time, content, and context and on that basis, Lilly denies the allegations. Lilly denies the remaining allegations in Paragraph 11.

12. In 2001, Lilly needed to fill the void left behind by Prozac's patent expiration, and so it sought approval by the Food and Drug Administration's ("FDA") for its next antidepressant, Cymbalta. Unlike Prozac, Cymbalta is a "Serotonin-Norepinephrine Reuptake Inhibitor" ("SNRI"), which Lilly promoted as increasing the brain chemicals serotonin and norepinephrine in the synaptic clefts between the neurons in the brain. Lilly and other SNRI manufacturers admit that the precise mechanism of action is not clear, however, they have promoted the drugs by stating that higher levels of these neurotransmitters somehow improve and elevate mood.

**ANSWER:** Lilly admits that Cymbalta® is a serotonin norepinephrine reuptake inhibitor ("SNRI"). Allegations pertaining to statements made about SNRIs are vague and

ambiguous as to time, content, and context and on that basis, Lilly denies the allegations. Lilly denies the remaining allegations in Paragraph 12.

13. In 2003, the FDA initially rejected Lilly's application to approve Cymbalta due to certain violations of good manufacturing practices and the risk of liver toxicity apparent in the drug's safety profile.

**ANSWER:** Lilly denies the allegations in Paragraph 13.

14. Eventually, in 2004, manufacturing issues were resolved and the FDA approved Cymbalta with a liver toxicity warning included in the prescribing information. The drug was approved for Major Depressive Disorder ("MDD"). In 2007, the FDA approved Cymbalta for treatment of Generalized Anxiety Disorder ("GAD") and in 2008 for treatment of fibromyalgia.

**ANSWER:** Lilly admits that the FDA approved Cymbalta® in 2004 for the treatment of Major Depressive Disorder ("MDD"). Lilly further admits that the FDA approved Cymbalta® for the treatment of Generalized Anxiety Disorder ("GAD") in 2007 and fibromyalgia in 2008. Lilly denies the remaining factual allegations in Paragraph 14.

15. Since the FDA's initial approval of Cymbalta in 2004, Lilly has aggressively marketed the drug to the public and the medical community, spending hundreds of millions of dollars each year on advertising and promotion. Lilly has promoted Cymbalta directly to consumers, including Plaintiff, through all major media channels, including internet, print and television. In addition, Lilly has promoted Cymbalta to the medical community by utilizing its well-organized army of sales representatives to personally visit physicians and health care professionals to distribute free drug samples and promotional literature. Lilly further promoted Cymbalta through advertisements in medical journals and presenting talks and exhibits at medical conferences.

**ANSWER:** Lilly admits that the FDA approved Cymbalta® in 2004. Lilly also admits that it researched, tested, developed, manufactured, labeled, marketed, and sold Cymbalta®, for use only upon a prescription by a licensed physician, in accordance with applicable laws and regulations, and for its approved indications with FDA-approved warnings, precautions, and other labeled risks and benefits of the medication. Lilly further admits that it promoted Cymbalta® to prescribers through its sales representatives. The allegations pertaining to the promotion of Cymbalta® utilizing Lilly sales representatives are vague and ambiguous as to time,

content, and context and on that basis, Lilly denies the allegations. Lilly denies the remaining allegations in Paragraph 15.

16. Lilly's promotional campaigns have continuously overstated the efficacy of Cymbalta and understated, downplayed, and/or failed altogether to state the true withdrawal side effects associated with Cymbalta.

**ANSWER:** Lilly denies the allegations in Paragraph 16.

17. Presently and at all times material herein, the Cymbalta label provided the following precaution regarding discontinuation: "Discontinuation symptoms have been systematically evaluated in patients taking duloxetine. Following abrupt or tapered discontinuation in placebo-controlled clinical trials, the following symptoms occurred at a rate greater than or equal to 1% and at a significantly higher rate in duloxetine-treated patients compared to those discontinuing from placebo: dizziness, nausea, headache, fatigue, paresthesia, vomiting, irritability, nightmares, insomnia, diarrhea, anxiety, hyperhidrosis and vertigo...."

**ANSWER:** Lilly admits that the Cymbalta® label has included a warning on discontinuation symptoms since Cymbalta® was approved by the FDA in 2004. Lilly admits that the Cymbalta® label contains the following "WARNINGS AND PRECAUTIONS" section regarding "Discontinuation of Treatment with Cymbalta®."

> Discontinuation symptoms have been systematically evaluated in patients taking duloxetine. Following abrupt or tapered discontinuation in placebo-controlled clinical trials, the following symptoms occurred at 1% or greater and at a significantly higher rate in duloxetine-treated patients compared to those discontinuing from placebo: dizziness, headache, nausea, diarrhea, paresthesia, irritability, vomiting, insomnia, anxiety, hyperhidrosis, and fatigue. During marketing of other SSRIs and SNRIs (serotonin and norepinephrine reuptake inhibitors), there have been spontaneous reports of adverse events occurring upon discontinuation of these drugs, particularly when abrupt, including the following: dysphoric mood, irritability, agitation, dizziness, sensory disturbances (e.g., paresthesias such as electric shock sensations), anxiety, confusion, headache, lethargy, emotional lability, insomnia, hypomania, tinnitus, and seizures. Although these events are generally self-limiting, some have been reported to be severe.
>
> Patients should be monitored for these symptoms when discontinuing treatment with Cymbalta®. A gradual reduction in the dose rather than abrupt cessation is recommended whenever possible. If intolerable symptoms occur following a decrease in

> the dose or upon discontinuation of treatment, then resuming the previously prescribed dose may be considered. Subsequently, the physician may continue decreasing the dose but at a more gradual rate . . . .

Paragraph 17 is vague and ambiguous as to time, content, and context and on that basis, Lilly denies the remaining allegations.

18. In addition to using the euphemistic term "discontinuation" to describe withdrawal side effects, Lilly also made it appear that such discontinuation symptoms were rare and only affected approximately 1% of Cymbalta users.

**ANSWER:** Lilly denies the allegations in Paragraph 18.

19. To the contrary, according to a January 2005 article published in the Journal of Affective Disorders, Lilly's Cymbalta clinical trials showed that a significant percentage (44.3%) of Cymbalta patients suffered from "discontinuation" side effects. David G. Peahia et al., Symptoms Following Abrupt Discontinuation of Duloxetine Treatment in Patients with Major Depressive Disorder, 89 JOURNAL OF AFFECTIVE DISORDERS 207 (2005). In this published, peer-reviewed paper, the withdrawal side-effect rates for Cymbalta were nearly double that experienced by placebo users, and these findings were statistically significant. Accordingly, the rate of withdrawal or "discontinuation" for Cymbalta (as established by Lilly's clinical trials) was 44.3%, yet in its packaging label, Lilly misleadingly presented this rate as approximately 1%.

**ANSWER:** The article cited speaks for itself, and Lilly denies any inaccurate characterization or interpretation of the article to which Plaintiff refer in Paragraph 19 of the Complaint when read in context and in its entirety. Lilly denies the remaining allegations in Paragraph 19.

20. Moreover, Lilly's clinical trials showed that, overall, 9.6% of Cymbalta users suffered severe withdrawal side effects, yet nowhere in the label does Lilly inform practitioners and patients of that risk.

**ANSWER:** Paragraph 20 is vague and ambiguous as to time, content, and context and on that basis, Lilly denies the allegations. Lilly denies the remaining allegations in Paragraph 20.

21. Cymbalta's withdrawal side effects include, among other things, headaches, dizziness, nausea, fatigue, diarrhea, paresthesia, vomiting, irritability, nightmares, insomnia, anxiety, hyperhidrosis, sensory disturbances, electric shock sensations, seizures and vertigo. When patients try to stop taking Cymbalta, the side effects can be severe enough to force them to start taking Cymbalta again, not to treat their underlying condition, but simply to stop the

withdrawal symptoms. Patients thus become prisoners to Cymbalta, and Lilly financially benefits by having a legion of physically dependent, long-term users of Cymbalta.

**ANSWER:** Lilly denies the allegations in Paragraph 21.

22. Notwithstanding Lilly's knowledge of the high rate of withdrawal symptoms in patients stopping Cymbalta, Lilly failed to adequately, properly, and fully warn patients and physicians about the risk.

**ANSWER:** Lilly denies the allegations in Paragraph 22.

23. Instead, in its product labeling, marketing and advertising, and in information made available to consumers and physicians, Lilly reported a far lower risk, downplayed any difference in the withdrawal risk for Cymbalta as compared to other similar antidepressants, and affirmatively misled the consuming patient population and mischaracterized the drug's risk profile.

**ANSWER:** Lilly denies the allegations in Paragraph 23.

24. In addition to failing to adequately warn about the actual rate and severity of withdrawal side effect risks, Lilly also overplayed the efficacy of Cymbalta. Seeking to capture a greater segment of the antidepressant market, in 2005, Lilly initiated the direct-to-consumer marketing campaign: "Depression hurts. Cymbalta can help." Cymbalta advertisements bearing this slogan appeared ubiquitously on television, in print and on the internet. Lilly's advertising campaign made it appear that Cymbalta not only treated depression but that it also treated physical pain associated with depression. Scientists reviewing the Cymbalta data have concluded that Lilly's claims are misleading. For example, in a 2008 article published in Psychotherapy and Psychosomatics, the author concluded that "the marketing of duloxetine as an antidepressant with analgesic properties for people with depression does not appear to be adequately supported."

**ANSWER:** Lilly admits that the marketing campaign for Cymbalta® included the statement "Depression hurts. Cymbalta® can help." Lilly denies the remaining characterization of Lilly's advertising and marketing campaign, objects to the statements being taken out of context, and denies the allegations on the basis that they are vague and ambiguous as to time, content, and context. The 2008 article cited is vague and ambiguous and no title is referenced and on that basis, Lilly denies the allegation. Lilly denies the remaining allegations in Paragraph 24.

25. Lilly has also augmented its misleading advertising campaigns by engaging in selective and biased publication of its clinical trials of Cymbalta. By way of example, Lilly has

generally published only favorable studies of its Cymbalta clinical trials and refused to publish any of the negative and unfavorable studies. Such selective publication of clinical trial data gives the impression that the drug is safer and more effective than it actually is. In a recent study published in the New England Journal of Medicine, researchers obtained clinical trials for antidepressants (including Cymbalta) that had been submitted to the FDA and compared them with studies that had been published. The authors found that there was a "bias towards the publication of positive results" and that, "according to the published literature, it appeared that 94% of the trials conducted were positive. By contrast, the FDA analysis shows that 51% were positive." The authors found that, as a result of such selective publication, the published literature conveyed a misleading impression of Cymbalta's efficacy resulting in an apparent effect-size that was 33% larger than the effect size derived from the full clinical trial data. See Erick H. Turner et al., Selective Publication of Antidepressant Trials and Its Influence on Apparent Efficacy, 358 NEW ENG. J. MED. 252 (2008).

**ANSWER:** The article cited speaks for itself, and Lilly denies any inaccurate characterization of interpretation of the article to which Plaintiff refer in Paragraph 25 of the Complaint when read in context and in its entirety. Lilly denies the remaining allegations in Paragraph 25.

26. Lilly's misleading direct-to-consumer promotional campaigns, its misleading presentation of Cymbalta's efficacy and its failure to adequately warn regarding Cymbalta's withdrawal and dependency side effects have paid off financially for Lilly. Cymbalta has become a "blockbuster" drug with over $3 billion dollars in annual sales. In the past few years, Cymbalta has been the second most profitable drug in Lilly's product line. Coincidently, the only drug ahead of Cymbalta is Zyprexa, an antipsychotic drug that Lilly promoted illegally. Indeed, in 2009, Lilly agreed to plead guilty and pay $1.415 billion to the federal government for illegally promoting Zyprexa. This resolution included a criminal fine of $515 million, which, at the time, was the largest settlement ever in a health care case, and the largest criminal fine for an individual corporation ever imposed in a United States criminal prosecution of any kind.

**ANSWER:** The allegations pertaining to the sales and profitability of Cymbalta® are vague and ambiguous as to time, content, and context and on that basis, Lilly denies the allegations. Lilly denies the remaining allegations in Paragraph 26 as characterized by Plaintiff.

27. Lilly had the knowledge, the means and the duty to provide adequate warnings regarding Cymbalta's common and severe withdrawal and dependency side effects as well as a duty to honestly portray the safety and efficacy of Cymbalta. Lilly could have relayed these warnings through the same means it utilized to advertise its products, which included but are not limited to its labeling, "Dear Doctor letters," advertisements and sales representatives.

**ANSWER:** Paragraph 27 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Lilly further denies it had a duty to warn consumers directly of alleged risks associated with the use of Cymbalta®. Lilly denies any remaining allegations in Paragraph 27.

28. In October 2012, the Institute for Safe Medication Practices (ISMP), a nonprofit healthcare consumer safety watchdog, issued findings from its independent investigation of Cymbalta adverse events found in the FDA Adverse Event Reporting System (FAERS). See QuarterWatch, Monitoring FDA MedWatch Reports, Why Reports of Serious Adverse Drug Events Continue to Grow, Oct. 3, 2012, ISMP.

**ANSWER:** The article cited speaks for itself, and Lilly denies any inaccurate characterization or interpretation of the article to which Plaintiff refer in Paragraph 28 of the Complaint when read in context and in its entirety.

29. The report announced that the investigation uncovered "a signal for serious drug withdrawal symptoms associated with duloxetine (CYMBALTA)," and detailed for the public what Lilly has long known: "[W]ithdrawal symptoms were reported in 44-50% of patients abruptly discontinuing duloxetine at the end of clinical studies for depression, and more than half of this total did not resolve within a week or two." *Id*. at 11.

**ANSWER:** The article cited speaks for itself, and Lilly denies any inaccurate characterization or interpretation of the article to which Plaintiff refer in Paragraph 29 of the Complaint when read in context and in its entirety. Lilly denies the remaining allegations in Paragraph 29.

30. The ISMP report continued: "[W]e identified a serious breakdown at both the FDA and the manufacturer, Eli Lilly and Company, in providing adequate warnings and instructions about how to manage this common adverse effect." *Id*.

**ANSWER:** The article cited speaks for itself, and Lilly denies any inaccurate characterization or interpretation of the article to which Plaintiff refer in Paragraph 30 of the Complaint when read in context and in its entirety. Lilly denies the remaining allegations in Paragraph 30.

31. Explaining the lack of adequate warnings, the ISMP stated:

> Instead of clear warnings and useful instructions, the duloxetine patient Medication Guide says only:
>
> > "Never stop an antidepressant medicine without first talking to a healthcare provider. Stopping an antidepressant medicine suddenly can cause other symptoms."
>
> This FDA-approved patient guide is materially deficient. It gives no hint of the persistence or severity of the symptoms known to occur.
>
> ....
>
> We could not identify any FDA-approved or company information for patients about how to discontinue duloxetine. *Id.* at 12-13.

**ANSWER:** The article cited speaks for itself, and Lilly denies any inaccurate characterization or interpretation of the article to which Plaintiff refer in Paragraph 31 of the Complaint when read in context and in its entirety. Lilly denies the remaining allegations in Paragraph 31.

32. In conclusion, the report minced no words in its indictment of Lilly's product information: "A major lapse has occurred in the FDA-approved information for patients about the risks of stopping duloxetine." *Id.* at 15.

**ANSWER:** The article cited speaks for itself, and Lilly denies any inaccurate characterization or interpretation of the article to which Plaintiff refer in Paragraph 32 of the Complaint when read in context and in its entirety. Lilly denies the remaining allegations in Paragraph 32.

33. Falsely reassured by the misleading and deceptive manner in which Lilly reported Cymbalta's withdrawal risk, physicians, including Plaintiff's physician, have prescribed, and continue to prescribe, Cymbalta to patients without adequate, accurate and proper warnings relating to discontinuation of the drug.

**ANSWER:** Lilly denies the allegations in Paragraph 33.

34. On or around August 10, 2006, Plaintiff was prescribed Cymbalta by his physician, for treatment of depression and fibromyalgia. Fibromyalgia is a long-term condition of chronic muscle, joint, and tendon pain throughout the body.

**ANSWER:** Lilly admits that fibromyalgia can be a long-term condition with symptoms that may include, but are not limited to, chronic muscle, joint, and tendon pain throughout the body. Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 34 pertaining to Plaintiff's Cymbalta® prescription and therefore denies the same. Lilly denies the remaining allegations in Paragraph 34.

35. On or around January 17, 2012 Plaintiff was concerned with the effects he experienced if he was late or missed a dose of Cymbalta. Under the care and supervision of his physician, Plaintiff elected to wean off of Cymbalta.

**ANSWER:** Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 35 and therefore denies the same.

36. Upon discontinuing Cymbalta, Plaintiff experienced severe and dangerous withdrawal symptoms. By way of example, Plaintiff experienced brain and body zaps, dizziness, nausea, vomiting, muscle spasms and pain, diarrhea, sweating, tremors, heart palpations, and insomnia.

**ANSWER:** Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 35 and therefore denies the same.

37. At all times relevant, Lilly knew or should have known that Cymbalta was in a defective condition and was and is inherently dangerous and unsafe when used in the manner instructed and provided for by Lilly.

**ANSWER:** Lilly denies the allegations in Paragraph 37.

38. At all times relevant, Lilly knew or should have known of the significantly increased risk of withdrawal symptoms, including their severity and duration, posed by Cymbalta and yet failed to adequately warn about said risks.

**ANSWER:** Lilly denies the allegations in Paragraph 38.

39. At all times relevant, Lilly engaged in a willful, wanton, and reckless conduct, including its defective design of Cymbalta, its failure to warn about Cymbalta's risks, and its pattern of affirmative misrepresentations and omissions relating to the safety and efficacy of Cymbalta. It overstated the drug's efficacy, downplayed withdrawal side effects, and misstated the actual risk and severity of side effects, all of which induced physicians to prescribe Cymbalta and consumers to use it, including Plaintiff and his physicians.

**ANSWER:** Lilly denies the allegations in Paragraph 39.

40. Plaintiff's use of the drug and consequent injuries and damages were a direct and proximate result of Lilly's acts and omissions relating to Cymbalta.

**ANSWER:** Paragraph 40 purports to allege conclusions of law and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 40 relating to Plaintiff's use of Cymbalta® and therefore denies the same.

41. If Lilly had adequately, accurately and properly warned about the withdrawal risk associated with Cymbalta, including the high risk of experiencing them and their frequency and severity, Plaintiff's physician would not have prescribed the drug to Plaintiff; Plaintiff would have refused the drug; and/or Plaintiff's physician would have been able to more adequately, accurately and properly weigh and convey the risks and benefits of the drug in a way as to avoid Plaintiff's injuries and damages.

**ANSWER:** Lilly denies the allegations in Paragraph 41.

42. As a direct and proximate result of taking Cymbalta, Plaintiff suffered compensable injuries, including but not limited to the following:

a. physical, emotional, and psychological injuries;

b. past and future pain and suffering;

c. past and future mental anguish;

d. loss of enjoyment of life;

e. past and future medical and related expenses; and

f. loss of consortium and companionship.

**ANSWER:** Paragraph 42(a) - (f) purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations relating to Plaintiff's alleged injuries and therefore denies the same.

**FIRST CAUSE OF ACTION**
**NEGLIGENCE**

43. Lilly reincorporates and realleges its Responses to Paragraphs 1-42 of Plaintiff's Complaint as if fully set forth herein.

44. Lilly owed to Plaintiff, and to other consumers and patients, a duty to exercise reasonable care in the design, formulation, manufacture, sale, promotion, supply and/or distribution of the drug Cymbalta, including the duty to assure that the product is as effective as it is promoted, that the product carries adequate warnings and that the product does not cause users to suffer from unreasonable, dangerous side effects.

**ANSWER:** Paragraph 44 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Lilly further denies it had a duty to warn consumers directly of alleged risks associated with the use of Cymbalta®.

45. Lilly was negligent in the design, manufacture, testing, advertising, marketing, promoting, labeling, supply, and sale of Cymbalta in that it:

a. Failed to provide proper warnings regarding the true frequency and severity of the withdrawal and dependency side effects associated with Cymbalta;

b. Failed to provide warnings that Cymbalta could cause patients to become physically dependent on Cymbalta;

c. Failed to provide adequate training and instructions to patients and health care professionals regarding appropriate uses and discontinuation of Cymbalta;

d. Failed to warn that the risks associated with Cymbalta exceeded the risks of other comparable forms of treatment;

e. Negligently misrepresented the efficacy of Cymbalta by portraying Cymbalta as being more efficacious than it really is;

f. Negligently designed Cymbalta in a way that it knew would cause withdrawal and physical dependency;

g. Negligently marketed Cymbalta despite the fact that the risk of the drug was so high and the benefits of the drug were so questionable that no reasonable pharmaceutical company, exercising due care, would have placed it on the market;

h. Recklessly, falsely, and deceptively represented or knowingly omitted, suppressed, or concealed, material facts regarding the safety and efficacy of Cymbalta to the Plaintiff, the public, the FDA and the medical community;

i. Failed to comply with its post-manufacturing duty to warn that Cymbalta was being promoted, distributed and prescribed without warning of the true risk of side effects and without accurate information regarding its efficacy; and

j. Was otherwise careless, negligent, grossly negligent, reckless, and acted with willful and wanton disregard for Plaintiff's rights and safety.

**ANSWER:** Paragraph 45 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Lilly denies the remaining factual allegations in Paragraph 45.

46. Despite the fact that Lilly knew, or should have known, that Cymbalta caused unreasonable, dangerous side effects, Lilly continued to market Cymbalta to consumers, including Plaintiff, when there were safer and more effective alternative methods and treatments. Lilly knew, or should have known, that Cymbalta users would suffer foreseeable injuries as a result of its failure to exercise ordinary care, as described above. Lilly knew or should have known that the Cymbalta designed, formulated, manufactured, and/or supplied by it was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation.

**ANSWER:** Paragraph 46 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Lilly further denies the remaining factual allegations in Paragraph 46.

47. Had Lilly provided an adequate warning regarding the frequency and severity of the withdrawal and dependency risks, Plaintiff's injuries would have been avoided.

**ANSWER:** Lilly denies the allegations in Paragraph 47. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 47 relating to Plaintiff's alleged injuries and therefore denies the same.

48. As a direct and proximate result of one or more of these wrongful acts and omissions of Lilly, Plaintiff suffered severe injuries as set forth herein. Plaintiff has incurred and will continue to incur physical and psychological pain and suffering, emotional distress, sorrow, anguish, stress, shock, and mental suffering. Plaintiff has required and will continue to require

healthcare and services and has incurred, and will continue to incur medical and related expenses. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages.

**ANSWER:** Paragraph 48 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 48 relating to Plaintiff's alleged injuries and therefore denies the same.

49. WHEREFORE, Plaintiff demand judgment against Lilly for compensatory, statutory and punitive damages, together with interest, costs of suit, and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

**ANSWER:** Lilly denies the allegations in Paragraph 49, except that Lilly admits only that Plaintiff seeks the relief set forth in Paragraph 49. Lilly denies that Plaintiff is entitled to any such relief.

**SECOND CAUSE OF ACTION**
**STRICT PRODUCT LIABILITY – DESIGN DEFECT**

50. Lilly reincorporates and realleges its Responses to Paragraphs 1-49 of Plaintiff's Complaint as if fully set forth herein.

51. At all times relevant, Lilly was engaged in the business of selling Cymbalta in the State of Louisiana.

**ANSWER:** Lilly admits that it has sold Cymbalta® in Louisiana, as alleged in Paragraph 51, and also in Wisconsin. Paragraph 51 is vague and ambiguous as to time and on that basis, Lilly denies the remaining allegations.

52. The Cymbalta manufactured, marketed, promoted and sold by Lilly was expected to, and did, reach Plaintiff without substantial change in the condition in which it was sold.

**ANSWER:** Lilly admits that it researched, tested, developed, manufactured, labeled, marketed, promoted, and sold Cymbalta®, for use only upon a prescription by a licensed physician, in accordance with applicable laws and regulations, and for its approved indications

with FDA-approved warnings, precautions, and other labeled risks and benefits of the medication. Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the remaining allegations in Paragraph 52 and therefore denies the same.

53. Lilly introduced a product into the stream of commerce that is dangerous and unsafe in that the harm of Cymbalta outweighs and benefit derived therefrom. The unreasonably dangerous nature of Cymbalta caused serious harm to Plaintiff.

**ANSWER:** Lilly denies the allegations in in Paragraph 53.

54. Lilly manufactured, marketed, promoted and sold a product that was merchantable and/or reasonably suited to the use intended, and its condition when sold was the proximate cause of the injuries sustained by Plaintiff.

**ANSWER:** Lilly admits that it researched, tested, developed, manufactured, labeled, marketed, promoted, and sold Cymbalta®, for use only upon a prescription by a licensed physician, in accordance with applicable laws and regulations, and for its approved indications with FDA-approved warnings, precautions, and other labeled risks and benefits of the medication. The remaining allegations pertaining to Lilly's "product" are vague and ambiguous as to time, content, and context, and on that basis, Lilly denies the allegations. Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations and legal conclusions in Paragraph 54 relating to Plaintiff's alleged injuries from Cymbalta® and therefore denies the same. Lilly denies the remaining allegations in Paragraph 54.

55. Lilly placed Cymbalta into the stream of commerce with wanton and reckless disregard for public safety.

**ANSWER:** Lilly denies the allegations in Paragraph 55.

56. Despite evidence that Cymbalta is dangerous and likely to place users at serious risk to their health, Lilly failed to disclose and warn of the health hazards and risks associated with Cymbalta and, in fact, acted to deceived the medical community and public at large, including all potential users of Cymbalta, by promoting it as safe and effective.

**ANSWER:** Lilly denies the allegations in Paragraph 56.

57. Lilly knew or should have known that physicians and other healthcare providers began commonly prescribing Cymbalta as a safe and effective product despite its lack of efficacy and potential for serious side effects.

**ANSWER:** Lilly denies the allegations in Paragraph 57.

58. There are other antidepressant medications and similar drugs on the market with safer alternative designs, in that they provide equal or greater efficacy and far less risk.

**ANSWER:** The allegations in Paragraph 58 are vague and ambiguous as to time, content, and context, and on that basis, Lilly denies the allegations.

59. As a direct and proximate result of Lilly's widespread promotional activity, physicians commonly prescribe Cymbalta and safe and effective.

**ANSWER:** Paragraph 59 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Moreover, the allegations in Paragraph 59 are vague and ambiguous as to time, content, and context, and on that basis, Lilly denies the allegations.

60. As a direct and proximate result of one or more of these wrongful acts and omissions of Lilly, Plaintiff suffered severe injuries as set forth herein. Plaintiff has incurred and will continue to incur physical and psychological pain and suffering, emotional distress, sorrow, anguish, stress, shock, and mental suffering. Plaintiff has required and will continue to require healthcare and services and has incurred, and will continue to incur medical and related expenses. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages.

**ANSWER:** Paragraph 60 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 60 relating to Plaintiff's alleged injuries and therefore denies the same.

61. WHEREFORE, Plaintiff demand judgment against Lilly for compensatory, statutory and punitive damages, together with interest, costs of suit, and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

**ANSWER:** Lilly denies the allegations in Paragraph 61, except that Lilly admits only that Plaintiff seeks the relief set forth in Paragraph 61. Lilly denies that Plaintiff is entitled to any such relief.

**THIRD CAUSE OF ACTION**
**STRICT PRODUCT LIABILITY – FAILURE TO WARN**

62. Lilly reincorporates and realleges its Responses to Paragraphs 1-61 of Plaintiff's Complaint as if fully set forth herein.

63. Lilly researched, tested, developed, designed, licensed, manufactured, packaged, inspected, labeled, distributed, sold, marketed, promoted and/or introduced Cymbalta into the stream of commerce and in the course of same, directly advertised and/or marketed Cymbalta to consumers or persons responsible for consumers, and therefore, had a duty to warn Plaintiff and Plaintiff's physicians of the risks associated with Cymbalta, which Lilly knew or should have known are inherent in the use of Cymbalta.

**ANSWER:** Lilly admits that it researched, tested, developed, manufactured, labeled, distributed, marketed, promoted, and sold Cymbalta®, for use only upon a prescription by a licensed physician, in accordance with applicable laws and regulations, and for its approved indications with FDA-approved warnings, precautions, and other labeled risks and benefits of the medication. Lilly further admits that it has utilized direct-to-consumer advertising for Cymbalta®, in conformity with applicable rules and regulations. Lilly objects to the term "persons responsible for consumers" as vague and ambiguous and on that basis denies the allegation. Paragraph 63 further purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Lilly denies the remaining allegations in Paragraph 63.

64. Lilly had a duty to warn of adverse drug reactions, which it knew or should have known, can be caused by the use of Cymbalta and/or are associated with the use of Cymbalta, including its propensity to induce withdrawal symptoms and side effects.

**ANSWER:** Paragraph 64 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations.

65. Cymbalta was under the exclusive control of Lilly and was not accompanied by appropriate warnings regarding all possible adverse side effects and complications associated with the use and discontinuation of Cymbalta. The information given to consumers and physicians did not accurately reflect the risk, incidence, symptoms, scope or severity of such side effects to the consumer as compared to other similar products available in the market, which possessed lower risk of such side effects. The promotional activities of Lilly further diluted and/or minimized any warnings that were provided with the product.

**ANSWER:** Plaintiff's allegation pertaining to "exclusive control" is vague and ambiguous as to time, content, and context and on that basis, Lilly denies the allegation. Lilly denies the remaining allegations in Paragraph 65.

66. Lilly downplayed the serious and dangerous side effects of Cymbalta in order to foster and heighten sales of the product.

**ANSWER:** Lilly denies the allegations in Paragraph 66.

67. Cymbalta was defective and unreasonably dangerous when it left the possession of Lilly in that it contained warnings insufficient to alert Plaintiff to the dangerous risks and reactions associated with it, including but not limited to severe, debilitating withdrawal symptoms. Even though Lilly knew or should have known the risks associated with Cymbalta, it failed to provide adequate warnings.

**ANSWER:** Paragraph 67 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Lilly denies the remaining allegations in Paragraph 67.

68. Plaintiff used Cymbalta as intended or in a reasonably foreseeable manner.

**ANSWER:** Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 68 relating to Plaintiff's alleged use of Cymbalta® and therefore denies the same.

69. Plaintiff could not have discovered any defect in the drug through the exercise of reasonable care.

**ANSWER:** Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations relating to Plaintiff or Plaintiff's physician's ability to

discover any alleged "defect in the drug" and therefore denies the same. Lilly denies any remaining allegations in Paragraph 69.

70. Lilly, as manufacturer of Cymbalta and other pharmaceutical prescription drugs, is held to the level of knowledge of an expert in the field, and further, Lilly had knowledge of the dangerous risks and side effects of Cymbalta.

**ANSWER:** Lilly admits that it is engaged in the business of researching, developing, testing, manufacturing, promoting, distributing, marketing, and selling prescription medications, including but not limited to Cymbalta®. Paragraph 70 purports to allege conclusions of law that do not require a response and on that basis, Lilly denies the allegations. Lilly denies the remaining factual allegations in Paragraph 70.

71. Plaintiff did not have the same knowledge as Lilly and no adequate warning was communicated to his physicians.

**ANSWER:** Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 71 relating to Plaintiff's knowledge and therefore denies the same. Lilly denies the remaining allegations in Paragraph 71.

72. Lilly had a continuing duty to warn consumers, including Plaintiff and his physicians, and the medical community of the dangers associated with Cymbalta and by negligently and wantonly failing to adequately warn of the dangers associated with the use of Cymbalta, Lilly breached its duty.

**ANSWER:** Paragraph 72 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Lilly denies the remaining factual allegations in Paragraph 72.

73. Although Lilly knew or should have known of the defective nature of Cymbalta, it continued to design, manufacture, market and sell the drug without providing adequate warnings or instructions concerning the use of the drug in order to maximize sales and profits at the expense of the public health and safety, in knowing, conscious, and deliberate disregard of the foreseeable harms posed by the drug.

**ANSWER:** Lilly denies the allegations in Paragraph 73.

74. In addition, Lilly's conduct in the packaging, warning, marketing, advertising, promoting, distribution, and sale of the drug was committed with knowing, conscious, willful, wanton, and deliberate disregard for the value of human life, and the rights and safety of consumers, including Plaintiff.

**ANSWER:** Lilly denies the allegations in Paragraph 74.

75. As a direct and proximate result of one or more of these wrongful acts and omissions of Lilly, Plaintiff suffered severe injuries as set forth herein. Plaintiff has incurred and will continue to incur physical and psychological pain and suffering, emotional distress, sorrow, anguish, stress, shock, and mental suffering. Plaintiff has required and will continue to require healthcare and services and has incurred, and will continue to incur medical and related expenses. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages.

**ANSWER:** Paragraph 75 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 75 relating to Plaintiff's alleged injuries and therefore denies the same.

76. WHEREFORE, Plaintiff demand judgment against Lilly for compensatory, statutory and punitive damages, together with interest, costs of suit, and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

**ANSWER:** Lilly denies the allegations in Paragraph 76, except that Lilly admits only that Plaintiff seeks the relief set forth in Paragraph 76. Lilly denies that Plaintiff is entitled to any such relief.

## FOURTH CAUSE OF ACTION
## STRICT PRODUCT LIABILITY

77. Lilly reincorporates and realleges its Responses to Paragraphs 1-76 of Plaintiff's Complaint as if fully set forth herein.

78. Lilly designed, manufactured, marketed, promoted, sold, supplied, and/or distributed Cymbalta in a defective and unreasonably dangerous condition to consumers, including Plaintiff.

**ANSWER:** Paragraph 78 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations.

79. Lilly designed, manufactured, marketed, promoted, sold, supplied, and/or distributed Cymbalta, which was expected to and did reach consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by Lilly.

**ANSWER:** Lilly admits that it researched, tested, developed, manufactured, labeled, marketed, promoted, and sold Cymbalta®, for use only upon a prescription by a licensed physician, in accordance with applicable laws and regulations, and for its approved indications with FDA-approved warnings, precautions, and other labeled risks and benefits of the medication. Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the remaining allegations in Paragraph 79 and therefore denies the same.

80. Plaintiff used Cymbalta as prescribed and in a manner normally intended, recommended, promoted, and marketed by Lilly.

**ANSWER:** Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 80 and therefore denies the same.

81. Cymbalta failed to perform safely when used by ordinary consumers, including Plaintiff, when used as intended and in a reasonably foreseeable manner.

**ANSWER:** Lilly denies the allegations in Paragraph 81.

82. Cymbalta was defective in its design and was unreasonably dangerous in that its foreseeable risks exceeded the benefits associated with its design and formulation.

**ANSWER:** Lilly denies the allegations in Paragraph 82.

83. Cymbalta was defective in design or formulation in that it posed a greater likelihood of injury compared to other similar medications and was more dangerous than an ordinary consumer could reasonably foresee or anticipate.

**ANSWER:** Lilly denies the allegations in Paragraph 83.

84. Cymbalta was defective in its design and was unreasonably dangerous in that it neither bore nor was packaged with, nor was otherwise accompanied by, warnings adequate to alert consumers, including Plaintiff and his physicians, of the risks described herein, including the significant increased risk of withdrawal symptoms.

**ANSWER:** Lilly denies the allegations in Paragraph 84.

85. Although Lilly knew or should have known of the defective nature of Cymbalta, it continued to design, manufacture, market, and sell Cymbalta in order to maximize sales and profits at the expense of the public health and safety. By so acting, Lilly acted with a conscious and deliberate disregard of the foreseeable harm caused by Cymbalta.

**ANSWER:** Lilly denies the allegations in Paragraph 85.

86. Plaintiff could not, through the exercise of reasonable care, have discovered Cymbalta's defects or perceived the dangers posed by the drug.

**ANSWER:** Lilly denies the allegations in Paragraph 86 concerning any alleged defect in Cymbalta®'s design and lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 86 concerning Plaintiff's state of mind.

87. Lilly's conduct as described herein was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Lilly and deter it from similar conduct in the future.

**ANSWER:** Lilly denies the allegations in Paragraph 87.

88. As a direct and proximate result of one or more of these wrongful acts and omissions of Lilly, Plaintiff suffered severe injuries as set forth herein. Plaintiff has incurred and will continue to incur physical and psychological pain and suffering, emotional distress, sorrow, anguish, stress, shock, and mental suffering. Plaintiff has required and will continue to require healthcare and services and has incurred, and will continue to incur medical and related expenses. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages.

**ANSWER:** Paragraph 88 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 88 relating to Plaintiff's alleged injuries and therefore denies the same.

89. WHEREFORE, Plaintiffs demands judgment against Lilly for compensatory, statutory and punitive damages, together with interest, costs of suit, and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

**ANSWER:** Lilly denies the allegations in Paragraph 89, except that Lilly admits only that Plaintiff seeks the relief set forth in Paragraph 89. Lilly denies that Plaintiff is entitled to any such relief.

**FIFTH CAUSE OF ACTION**
**NEGLIGENT MISREPRESENTATION**

90. Lilly reincorporates and realleges its Responses to Paragraphs 1-89 of Plaintiff's Complaint as if fully set forth herein.

91. Lilly owed a duty to Plaintiff and his physicians to convey and communicate truthful and accurate information about Cymbalta.

**ANSWER:** Paragraph 91 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations.

92. Lilly represented to Plaintiff, his physicians, and other members of the public and the medical community that Cymbalta was safe for use and that any withdrawal side effects were no different, and no worse and no more frequent, than other similar products in the market. These representations were, in fact, false.

**ANSWER:** Lilly denies the allegations in Paragraph 92.

93. Lilly also represented to Plaintiff, his physicians, and other members of the public and the medical community that Cymbalta can treat physical pain associated with depression. These representations were, in fact, false.

**ANSWER:** Lilly denies the allegations in Paragraph 93.

94. Lilly was negligent in failing to exercise due care in making the aforesaid representations.

**ANSWER:** Paragraph 94 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Lilly denies the remaining factual allegations.

95. Lilly had a pecuniary interest in making said representations, which were made in order to expand sales and increase revenue Cymbalta.

**ANSWER:** Lilly denies the allegations in Paragraph 95.

96. At the time said representations were made by Lilly, at the time Plaintiff and his physicians took the actions herein alleged, Plaintiff and his physicians were ignorant of the falsity of Lilly's representations and reasonably believed them to be true. In justifiable reliance upon said representations, Plaintiff and his physicians were induced to, and did, use Cymbalta and attempt to discontinue from Cymbalta. If Plaintiff and his physicians had known the actual facts, Plaintiff's injuries would have been avoided because Plaintiff's physician would not have prescribed the drug, Plaintiff would not have taken the drug, and/or the risk would have been conveyed to Plaintiff in a way so as to alter the prescription and avoid Plaintiff's injuries.

**ANSWER:** Lilly denies the allegations in Paragraph 96. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 96 relating to Plaintiff and/or his physicians' alleged actions, knowledge, beliefs, and injuries and therefore denies the same.

97. The reliance of Plaintiff and his physicians upon Lilly's representations was justified because the representations were made by individuals and entities that appeared to be in a position to know the true facts relating to risks associated with Cymbalta.

**ANSWER:** Paragraph 97 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 97 and therefore denies the same.

98. As a direct and proximate result of one or more of these wrongful acts and omissions of Lilly, Plaintiff suffered pecuniary losses including but not limited to past and future medical and related expenses.

**ANSWER:** Paragraph 98 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 98 relating to Plaintiff's alleged injuries and therefore denies the same.

99. WHEREFORE, Plaintiff demand judgment against Lilly for compensatory, statutory and punitive damages, together with interest, costs of suit, and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

**ANSWER:** Lilly denies the allegations in Paragraph 99, except that Lilly admits only that Plaintiff seeks the relief set forth in Paragraph 99. Lilly denies that Plaintiff is entitled to any such relief.

**SIXTH CAUSE OF ACTION**
**FRAUD**

100. Lilly reincorporates and realleges its Responses to Paragraphs 1-99 of Plaintiff's Complaint as if fully set forth herein.

101. Lilly represented to Plaintiff, his physicians, and other members of the public and the medical community that Cymbalta was safe for use and that any withdrawal side effects were no different, and no worse and no more frequent, than other similar products in the market. These representations were, in fact, false and material.

**ANSWER:** Lilly denies the factual allegations in Paragraph 101. To the extent the Paragraph 101 purports to allege conclusions of law that do not require a response, Lilly further denies those allegations.

102. Lilly also represented to Plaintiff, his physicians, and other members of the public and the medical community that Cymbalta can treat physical pain associated with depression. These representations were, in fact, false and material.

**ANSWER:** Lilly denies the factual allegations in Paragraph 102. To the extent the Paragraph 102 purports to allege conclusions of law that do not require a response, Lilly further denies those allegations.

103. Lilly made the aforesaid representations knowingly and/or with reckless disregard for their truth or falsity.

**ANSWER:** Lilly denies the factual allegations in Paragraph 103. To the extent the Paragraph 103 purports to allege conclusions of law that do not require a response, Lilly further denies those allegations.

104. Lilly made the aforesaid representations with the intent that Plaintiff and his physicians act upon said representations.

**ANSWER:** Lilly denies the factual allegations in Paragraph 104. To the extent the Paragraph 104 purports to allege conclusions of law that do not require a response, Lilly further denies those allegations.

105. At the time said representations were made by Lilly, at the time Plaintiff and his physicians took the actions herein alleged, Plaintiff and his physicians were ignorant of the falsity of Lilly's representations and reasonably believed them to be true. In justifiable reliance upon said representations, Plaintiff and his physicians were induced to, and did, use Cymbalta and attempt to discontinue from Cymbalta. If Plaintiff and his physicians had known the actual facts, Plaintiff's injuries would have avoided because either Plaintiff's physician would not have prescribed the drug, Plaintiff would not have taken the drug, and/or the risk would have been conveyed to Plaintiff in a way so as to alter the prescription and avoid Plaintiff's injuries.

**ANSWER:** Lilly denies the factual allegations in Paragraph 105. To the extent the Paragraph 105 purports to allege conclusions of law that do not require a response, Lilly further denies those allegations.

106. The reliance of Plaintiff and his physicians upon Lilly's representations was justified because the representations were made by individuals and entities who appeared to be in a position to know the true facts relating to risks associated with Cymbalta.

**ANSWER:** Paragraph 106 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 106 and therefore denies the same.

107. As a direct and proximate result of one or more of these wrongful acts and omissions of Lilly, Plaintiff suffered severe injuries as set forth herein. Plaintiff has incurred and will continue to incur physical and psychological pain and suffering, emotional distress, sorrow, anguish, stress, shock, and mental suffering. Plaintiff has required and will continue to require healthcare and services and has incurred, and will continue to incur medical and related expenses. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages.

**ANSWER:** Paragraph 107 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or

information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 107 relating to Plaintiff's alleged injuries and therefore denies the same.

108. WHEREFORE, Plaintiff demand judgment against Lilly for compensatory, statutory and punitive damages, together with interest, costs of suit, and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

**ANSWER:** Lilly denies the allegations in Paragraph 108, except that Lilly admits only that Plaintiff seeks the relief set forth in Paragraph 108. Lilly denies that Plaintiff is entitled to any such relief.

**SEVENTH CAUSE OF ACTION**
**BREACH OF IMPLIED WARRANTY**

109. Lilly reincorporates and realleges its Responses to Paragraphs 1-108 of Plaintiff's Complaint as if fully set forth herein.

110. As described herein, Plaintiff suffered injuries as a direct and proximate result of his use and discontinuation of Cymbalta.

**ANSWER:** Paragraph 110 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 110 relating to Plaintiff's alleged injuries or Plaintiff's alleged "use and discontinuation" of Cymbalta® and therefore denies the same.

111. At the time of Plaintiff's use of Cymbalta and resulting injuries, the Cymbalta he was taking was in essentially the same condition as when it left the control and possession of Lilly.

**ANSWER:** Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 111 and therefore denies the same.

112. At all times relevant, the Cymbalta received and used by Plaintiff was not fit for the ordinary purposes for which it is intended to be used in that, inter alia, it posed a higher risk of withdrawal symptoms – of greater duration and severity – than other similar products available in the market.

**ANSWER:** Paragraph 112 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Lilly denies the remaining factual allegations.

113. Plaintiff's injuries were due to the fact that Cymbalta was in a defective condition, as described herein, rendering it unreasonably dangerous to him.

**ANSWER:** Paragraph 113 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 113 relating to Plaintiff's injuries and therefore denies the same.

114. As a direct and proximate result of one or more of these wrongful acts and omissions of Lilly, Plaintiff suffered severe injuries as set forth herein. Plaintiff has incurred and will continue to incur physical and psychological pain and suffering, emotional distress, sorrow, anguish, stress, shock, and mental suffering. Plaintiff has required and will continue to require healthcare and services and has incurred, and will continue to incur medical and related expenses. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages.

**ANSWER:** Paragraph 114 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 114 relating to Plaintiff's alleged injuries and therefore denies the same.

115. WHEREFORE, Plaintiff demand judgment against Lilly for compensatory, statutory and punitive damages, together with interest, costs of suit, and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

**ANSWER:** Lilly denies the allegations in Paragraph 115, except that Lilly admits only that Plaintiff seeks the relief set forth in Paragraph 115. Lilly denies that Plaintiffs is entitled to any such relief.

**EIGHTH CAUSE OF ACTION**
**UNLAWFUL, UNFAIR AND FRAUDULENT BUSINESS PRACTICES IN VIOLATION OF WISCONSIN CONSUMER ACT, W.S.A. 100.20, *et seq.***

116. Lilly reincorporates and realleges its Responses to Paragraphs 1-115 of Plaintiff's Complaint as if fully set forth herein.

117. Wisconsin Consumer Act creates a cause of action for those harmed by unfair competition, which includes "unfair methods of competition in business and unfair trade practices in business."

**ANSWER:** Paragraph 117 states legal conclusions to which no responses is required. To the extent a response may be deemed necessary, Lilly denies the allegations in Paragraph 117, except that Lilly admits only that Paragraph 117 purports to paraphrase and characterize a portion of the Wisconsin Consumer Act, which speaks for itself.

118. Defendant has made numerous misrepresentations to Plaintiff, his healthcare providers, and the general public.

**ANSWER:** Lilly denies the allegations in Paragraph 118.

119. Defendant has made numerous misleading omissions, including their failure to disclose risk information as described herein, thereby giving rise to unnecessary pain and suffering.

**ANSWER:** Lilly denies the allegations in Paragraph 119.

120. Defendant's business practices relating to their products are unlawful because they constitute, inter alia, false advertising, intentional misrepresentation and fraudulent concealment.

**ANSWER:** Paragraph 120 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Lilly denies the remaining factual allegations.

121. As a direct and proximate result of Defendant's unlawful business practices and false advertising, Plaintiff has suffered significant damages, including but not limited to physical injury and actual loss of money or property, and will continue to suffer such damages in the future.

**ANSWER:** Paragraph 121 purports to allege conclusions of law that do not require a response and on that basis Lilly denies the allegations. Moreover, Lilly lacks knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations in Paragraph 121 relating to Plaintiff's alleged injuries.

122. WHEREFORE, Plaintiff seeks damages, restitution, disgorgement, injunctive relief, attorneys' fees and costs, and all other relief allowed under Wisconsin Consumer Act, *W.S.A. 100.20, et. seq.*

**ANSWER:** Lilly denies the allegations in Paragraph 122, except that Lilly admits only that Plaintiff seeks the relief set forth in Paragraph 122. Lilly denies that Plaintiff is entitled to any such relief.

Lilly denies each and every allegation in Plaintiff's Complaint not specifically admitted herein.

**PRAYER FOR RELIEF**

Lilly denies the allegations in this section of Plaintiff's Complaint, except that Lilly admits only that Plaintiff seek the relief set forth in this section. Lilly denies that Plaintiff is entitled to any relief whatsoever.

**DEMAND FOR JURY TRIAL**

This section of Plaintiff's Complaint does not assert any allegation requiring a response. To the extent a response is deemed necessary, Lilly admits that Plaintiff request a trial by jury.

**GENERAL DENIAL AND DEFENSES**

Discovery and investigation may reveal that any one or more of the following defenses should be available to Lilly in this matter. Lilly, therefore, asserts said defenses in order to preserve the right to assert them. Upon completion of discovery, and if the facts warrant, Lilly may withdraw any of these defenses as may be appropriate. Further, Lilly reserves the right to amend its Answer to assert additional defenses, cross-claims, counterclaims, and other claims

and defenses as discovery proceeds. Further answering and by way of additional defense, Lilly states the following:

**FIRST DEFENSE**

One or more claims asserted or raised in the Complaint is barred by the applicable statute of limitations and is otherwise untimely.

**SECOND DEFENSE**

The Complaint, including Plaintiffs' claim under the Wisconsin Consumer Act, Wis. Stat. § 100.20 *et seq*., fails to state a claim upon which relief can be granted.

**THIRD DEFENSE**

Each and every claim asserted or raised in the Complaint is barred by the doctrines of estoppel, waiver or statutory and regulatory compliance.

**FOURTH DEFENSE**

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries or losses were caused in whole or in part through the operation of nature or other intervening or superseding cause or causes.

**FIFTH DEFENSE**

To the extent that Plaintiff assert claims based upon an alleged failure by Lilly to warn Plaintiff directly of alleged dangers associated with the use of Cymbalta®, such claims are barred under the learned intermediary doctrine because Lilly has discharged its duty to warn in its warnings to the prescribing physician.

**SIXTH DEFENSE**

To the extent that Plaintiff asserts claims based on Lilly's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Supremacy Clause of the United States Constitution.

**SEVENTH DEFENSE**

Plaintiff has not sustained an ascertainable loss of property or money.

**EIGHTH DEFENSE**

Any liability that might otherwise be imposed upon this Defendant is barred or subject to reduction by application of Wis. Stat. § 895.045.

**NINTH DEFENSE**

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses were only sustained after Plaintiff knowingly, voluntarily, and willfully assumed the risk of any injury as the result of the consumption of, administration of, or exposure to any medicine or pharmaceutical preparation manufactured or distributed by Lilly or other manufacturer.

**TENTH DEFENSE**

If Plaintiff have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Lilly and over whom Lilly had not control and for whom Lilly may not be held accountable.

**ELEVENTH DEFENSE**

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by Plaintiff's misuse or abuse of Cymbalta®.

**TWELFTH DEFENSE**

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from Plaintiff's pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases, or illnesses, idiosyncratic reactions, subsequent medical conditions or natural course of conditions for which this Defendant is not responsible.

**THIRTEENTH DEFENSE**

To the extent that Plaintiff rely upon any theory of breach of warranty, such claims are also barred for lack of timely notice of breach and/or lack of privity.

**FOURTEENTH DEFENSE**

Plaintiff's claims are barred, in whole or in part, because Plaintiff did not rely on any act, omission, or representation made by Lilly.

**FIFTEENTH DEFENSE**

To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused the injuries asserted in the Complaint, such an award would, if granted, violate Lilly's state and federal rights.

**SIXTEENTH DEFENSE**

No act or omission of Lilly was willful, wanton, reckless or grossly negligent and, therefore, any award of punitive damages is barred.

**SEVENTEENTH DEFENSE**

Plaintiff have not suffered any actual injury or damages.

**EIGHTEENTH DEFENSE**

Plaintiff's claims are barred in whole or in part because Lilly provided legally adequate "directions or warnings" as to the use of Cymbalta® and any other medicine or pharmaceutical preparation Plaintiff alleges to have taken within the meaning of Comment j to Section 402A of the RESTATEMENT OF (SECOND) OF TORTS.

**NINETEENTH DEFENSE**

Plaintiff's claims are barred under Section 4, *et seq.*, of the RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY.

**TWENTIETH DEFENSE**

Plaintiff's claims are barred under comment f to Section 6 of the RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY.

**TWENTY-FIRST DEFENSE**

There is no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of Cymbalta®. Plaintiff's causes of action are barred in whole or in part by their failure to assert a safer design for Cymbalta®.

**TWENTY-SECOND DEFENSE**

Plaintiff's claims are barred in whole or in part by failure to mitigate damages.

**TWENTY-THIRD DEFENSE**

Plaintiff's claims are barred in whole or in part because Lilly's conduct conforms with medical knowledge.

**TWENTY-FOURTH DEFENSE**

With respect to each and every cause of action, Plaintiff is not entitled to recover for strict liability because Plaintiff cannot state claims founded in strict liability because, among other things, comments j and k to Section 402A of the RESTATEMENT (SECOND) OF TORTS relegates Plaintiff's claims to a negligence cause of action.

**TWENTY-FIFTH DEFENSE**

With respect to each and every cause of action, Plaintiff is not entitled to recover because if the product involved was unsafe, which Lilly denies, then it was unavoidably unsafe as defined in the RESTATEMENT OF TORTS. The apparent benefits of the product exceeded any apparent risk given the scientific knowledge available when the product was marketed.

**TWENTY-SIXTH DEFENSE**

Lilly's advertisement and labeling with respect to the products which are the subject matter of this action were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States and Wisconsin Constitutions.

**TWENTY-SEVENTH DEFENSE**

The public interest in the benefit and availability of the product which is the subject matter of this action precludes liability for risks, if any, resulting from any activities undertaken by Defendant, which were unavoidable given the state of human knowledge at the time those activities were undertaken. With respect to Plaintiff's claims, if it is determined there is a risk inherent in the product which is the subject matter of this action, then such risk, if any, is outweighed by the benefit of the product.

**TWENTY-EIGHTH DEFENSE**

Lilly made no warranties of any kind, express or implied, including any alleged implied warranty of merchantability or any representations of any nature whatsoever to the Plaintiff.

**TWENTY-NINTH DEFENSE**

At all times relevant herein, any product which is the subject matter of this action manufactured and distributed by Lilly in any state in the United States was manufactured and distributed in a reasonable and prudent manner based upon available medical and scientific knowledge and further was processed and distributed in accordance with and pursuant to all applicable regulations of the FDA.

**THIRTIETH DEFENSE**

With respect to each and every purported cause of action, the acts of Lilly were at all times done in good faith and without malice.

**THIRTY-FIRST DEFENSE**

To the extent there were any risks associated with the use of the product which is the subject matter of this action which Lilly knew or should have known and which gave rise to a duty to warn, Lilly at all times discharged such duty through appropriate and adequate warnings in accordance with federal and state law.

**THIRTY-SECOND DEFENSE**

Plaintiff's claims against Lilly are barred because Plaintiff's treating physicians fully informed Plaintiff of the risks associated with the use of Cymbalta®. Any informed consent and/or release given by Plaintiff is pleaded as an affirmative defense.

**THIRTY-THIRD DEFENSE**

To the extent Plaintiff's claims are based on alleged misrepresentations made to the FDA, such claims are barred pursuant to *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2000).

**THIRTY-FOURTH DEFENSE**

Plaintiff's claims for pre-judgment and post-judgment interest are limited by Wis. Stat. § 807.01(4); Wis. Stat. § 814.04(4); and Wis. Stat. § 815.05(8).

**THIRTY-FIFTH DEFENSE**

Plaintiff's damages claims are barred by the economic loss doctrine.

**THIRTY-SIXTH DEFENSE**

Plaintiff's claims of fraud are barred by reason of the Complaint's failure to allege the factual circumstances constituting the alleged fraud with particularity.

**THIRTY-SEVENTH DEFENSE**

Lilly fully asserts Wis. Stat. § 895.047(3)(b) and states that Cymbalta® complied in material respects with relevant standards, conditions, and specifications adopted or approved by

the federal government that were applicable to the product at the time of manufacture and that governed the product risk that allegedly caused harm.

**THIRTY-EIGHTH DEFENSE**

Plaintiff's claims may be barred by failure to join indispensable parties.

**THIRTY-NINTH DEFENSE**

Any claims relating to alleged communications with regulatory agencies of the U.S. government are barred in whole or in part by operation of Lilly's First Amendment right to petition the government (the *Noerr-Pennington* Doctrine).

**FORTIETH DEFENSE**

To the extent Plaintiff asserts demand for punitive damages, Lilly specifically incorporates by reference any and all standards of limitations regarding the determination and/or enforceability of punitive damages awards that arose in the decisions of *BMW of No. America v. Gore*, 517 U.S. 559 (1996); *Cooper Industries,* Inc*. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); *State Farm Mut. Auto Ins. Co. v. Campbell*, 123 S. Ct. 1513 (2003); and *Exxon Shipping Co. v. Baker*, No. 07-219, 2008 U.S. LEXIS 5263 (U.S. June 25, 2008) and their progeny as well as other similar cases under both federal and state law.

**FORTY-FIRST DEFENSE**

Any claim for punitive damages is limited by WIS. STAT. § 895.043(3), which requires proof "that the defendant acted maliciously toward the plaintiff or in an intentional disregard of the rights of the plaintiff."

**FORTY-SECOND DEFENSE**

To the extent that Plaintiff asserts a claim for punitive damages, that claim is in contravention of the rights of Lilly under the following constitutional provisions:

a. Plaintiff's claim for punitive damages violates, and is therefore barred by, the Fourth, Fifth, Sixth, Eighth and Fourteenth Amendments to the Constitution of the United States of America, and the analogous provisions of the Wisconsin Constitution, on grounds including the following:

i. the procedures pursuant to which punitive damages are awarded fail to provide specific standards for the amount of the award of punitive damages which thereby violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution, and the analogous provisions of the Wisconsin Constitution;

ii. the procedures pursuant to which punitive damages are awarded result in the imposition of different penalties for the same or similar acts, and thus violate the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution, and the analogous provisions of the Wisconsin Constitution;

iii. the procedures pursuant to which punitive damages are awarded permit the imposition of punitive damages in excess of the maximum criminal fine for the same or similar conduct, which thereby infringes upon the Due Process Clause of the Fifth and Fourteenth Amendments and the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution, and the analogous provisions of the Wisconsin Constitution;

iv. the procedures pursuant to which punitive damages are awarded permit the imposition of excessive fines in violation of the Eighth Amendment of the United States Constitution, and the analogous provisions of the Wisconsin Constitution;

v. the award of punitive damages to Plaintiff in this action would constitute a deprivation of property without due process of law; and

vi. the procedures pursuant to which punitive damages are awarded permit the imposition of an excessive fine and penalty.

**FORTY-THIRD DEFENSE**

Any claim for punitive damages is limited by Wis. Stat §895.043(6) to two times the amount of compensatory damages or $200,000.00, whichever is greater. Lilly asserts all other defenses and limitations on punitive damages contained in Wis. Stat §895.043.

**FORTY-FOURTH DEFENSE**

The determination of the amount of punitive damages, if any, should be bifurcated from the remaining issues pursuant to Wis. Stat. § 805.05(2) and *Russell v. Wisconsin Mut. Ins. Co.*, 214 Wis. 2d 591, 571 N.W.2d 924 (Wis. Ct. App. 1997).

**FORTY-FIFTH DEFENSE**

Plaintiff's claims are barred, in whole or in part, because Cymbalta® was designed, manufactured, distributed, marketed, and labeled with proper warnings, information, cautions, and instructions, in accordance with the state of the art and the state of scientific and technological knowledge. Lilly invokes all state of the art defenses applicable to Plaintiff's claims, including the state of the art applicable to the industry in question, medicine, medical science, and all others, alleging that it discharged, according to law and due care, each and every duty which Plaintiff may have been owed.

Inasmuch as the Complaint does not describe the alleged underlying claims with sufficient particularity to enable Lilly to determine all of its legal, contractual, and equitable rights, Lilly reserves the right to amend and/or supplement the averments of its Answer to assert any and all pertinent liability defenses ascertained through further investigation and discovery.

Lilly will rely on all defenses that may become available during discovery or trial.

WHEREFORE, Lilly respectfully demands judgment dismissing the Complaint with prejudice and awarding Lilly its reasonable costs and disbursements, including reasonable attorneys' fees, together with such and other and further relief that the court may deem just and proper.

**JURY DEMAND**

Lilly demands a trial by jury as to all issues triable.

Dated: January 16, 2015

Respectfully submitted,

*/s/ Naikang Tsao*

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